UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,150	07/17/2003	Robert W. Childers	3712044-00440	5656

29200 7590 12/30/2009

K&L Gates LLP
P.O. Box 1135
Chicago, IL 60690-1135

EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
12/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/624,150	CHILDERS ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the last three to four lines of each of claims 1, 13 and 24 recite "the dialysate is drained from the fluid circuit at a discharge rate that is less than the circulation rate allowing/effective to cause/effective to circulate the dialysate a plurality of times along the fluid loop prior to discharge". The specification lacks antecedent basis for this cause and effect relationship recited in the claims.

Claim Rejections - 35 USC § 112

Claims 1, 13, 24 and consequently all dependent claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claim 1, the last four lines of the claim read "the dialysate is drained from the fluid circuit at a discharge rate that is less than the circulation rate allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge". It does not appear, after reviewing Applicant's specification and figures, that

Applicant has support for the creation of the dialysate to be circulated around the fluid loop a plurality of times due expressly to the draining the dialysate at a rate lower than the circulation rate. The examiner has not been able to find support in the specification for this direct cause and effect relationship (i.e. a lower discharge rate causing circulation along the loop a plurality of times). Rather, the examiner has found support for multiple embodiments in which at the very least, a pump is employed to help with the higher circulation rate and thus the multiple circulation loops (all figures of Applicant's drawings include at least one pump/cycler). Furthermore, paragraph [0075] discloses that various pumps, valves, sensing devices and other fluid circuit components can be employed to help control the flow the dialysate multiple times around the fluid loop. Please also see the examiner's response to arguments section at the end of the office action.

With respect to claim 13, the last four lines of the claim read "the dialysate is drained from the fluid circuit at a discharge rate effective to cause the dialysate to be circulated a plurality of times along the fluid loop prior to discharge". It does not appear, after reviewing Applicant's specification and figures, that Applicant has support for the creation of the dialysate to be circulated around the fluid loop a plurality of times due expressly to the draining the dialysate at a rate lower than the circulation rate. The examiner has not been able to find support in the specification for this direct cause and effect relationship (i.e. a lower discharge rate causing circulation along the loop a plurality of times). Rather, the examiner has found support for multiple embodiments in which at the very least, a pump is employed to help with the higher circulation rate and

thus the multiple circulation loops (all figures of Applicant's drawings include at least one pump/cycler). Furthermore, paragraph [0075] discloses that various pumps, valves, sensing devices and other fluid circuit components can be employed to help control the flow the dialysate multiple times around the fluid loop. Please also see the examiner's response to arguments section at the end of the office action.

With respect to claim 24, the last three lines of the claim read "the dialysate is drained at a discharge rate effective to circulate the dialysate a plurality of times along the fluid loop prior to discharge". It does not appear, after reviewing Applicant's specification and figures, that Applicant has support for the creation of the dialysate to be circulated around the fluid loop a plurality of times due expressly to the draining the dialysate at a rate lower than the circulation rate. The examiner has not been able to find support in the specification for this direct cause and effect relationship (i.e. a lower discharge rate causing circulation along the loop a plurality of times). Rather, the examiner has found support for multiple embodiments in which at the very least, a pump is employed to help with the higher circulation rate and thus the multiple circulation loops (all figures of Applicant's drawings include at least one pump/cycler). Furthermore, paragraph [0075] discloses that various pumps, valves, sensing devices and other fluid circuit components can be employed to help control the flow the dialysate multiple times around the fluid loop. Please also see the examiner's response to arguments section at the end of the office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu et al. (US Patent No. 6254567) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Treu discloses the device substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 2), the system comprising: a catheter having an inflow lumen and an outflow lumen (Fig. 2 discloses an embodiment which uses a double lumen catheter 18) in communication with the patient's peritoneal cavity (20); and a fluid circuit (Fig. 2) in fluid communication with the catheter, the fluid circuit including: a fluid loop (10), the fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (the dialysate follows the path through the loop 10 multiple times as it is regenerated); a supply of dialysate coupled to the fluid circuit; at least one of a chamber

coupled to the fluid loop through which the dialysate can be fed at a feed rate into the fluid loop (88 allows the dialysate to be fed back into the fluid loop via the actions of the valves), and a cleaning device (22) coupled to the fluid loop via a cleaning fluid path (the path includes entering the cleaning device via 32, flowing through the cleaning device and re-entering the fluid loop via 34) wherein the dialysate can be fed into the cleaning fluid path and cleaned at a cleaning rate prior to reintroduction into the fluid loop (please note that the claim language does not require that the cleaning rate be a specific rate relative to any other rate claimed, therefore the rate at which the fluid flows through the cleaning device is being interpreted as the cleaning rate); a cycler (12) that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient (please note that the claim language does not require that the feed rate and circulation rates be specific rates as compared to other rates in the claim); and a discharge fluid path (fluid path leading to 46) coupled to the fluid loop through which the dialysate is drained from the fluid circuit at a discharge rate. Treu, however, does not disclose that the fluid is drained at a discharge rate that is less than the circulation rate allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. Roberts, however, discloses a similar fluid loop in which the fluid is drained at a rate less than the circulation rate thus allowing the fluid to circulate a plurality of times along the fluid loop prior to being drained (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a

higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. This paragraph also corresponds to the second paragraph in the second column of page 374 in which circulation rates and inflow/outflow rates are disclosed.). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Treu with the lower discharge rate as taught by Roberts, in order to allow the fluid to be used the maximum amount possible before being drained as waste. Also it is the examiner's position that it would be obvious to use the teaching by Roberts to drain the fluid at a rate that is slower than the circulation rate, as this is only a change to the rates at which the system/fluid flow is operated, and constitutes only finding an optimum value of a result effective variable which is routine in the art.

In reference to claim 2, Treu discloses at least one pressure sensor coupled to the fluid circuit for sensing a pressure (76, 78).

In reference to claim 5, Treu discloses that the cycler comprises two pumps (Fig. 5 discloses an embodiment in which there are two pumps (70 and 100)).

In reference to claim 6, Treu discloses that the cleaning device contains sorbents for adsorbing at least one of urea, phosphate and creatinine (col. 1 lines 25-26 disclose that the waste products removed by the cleaning device include urea and creatinine).

In reference to claim 7, Treu discloses that the cleaning device contains an ion exchange resin (col. 1, line 24).

In reference to claim 8, Treu discloses that the cleaning device contains at least one electrolyte for addition to the dialysate (col. 8, lines 58-61).

In reference to claim 9, Treu discloses that the cleaning device contains at least three layers (col. 4, lines 24-41).

In reference to claim 10, Treu discloses the chamber (88) allowing the fluid loop to accommodate a variable increase in the dialysate during treatment (Fig. 2).

In reference to claim 11, Roberts discloses that the increase is due to an addition of ultrafiltrate to the fluid loop (paragraph 2, col. 2 of page 374).

In reference to claim 12, Treu discloses at least one valve connecting the catheter to the fluid circuit (80 and 92 in Fig. 2).

Claims 13, 14, 16-18, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu et al. (US Patent No. 6254567) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Treu discloses the device substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 2), the system comprising: a catheter having an inflow lumen and an outflow lumen (Fig. 2 discloses an embodiment which uses a double lumen catheter 18) in communication with the patient's peritoneal cavity (20); and a fluid circuit (Fig. 2) in fluid communication with the catheter, the fluid circuit comprising: a fluid loop (10), the fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (the dialysate follows the path through the loop 10 multiple times as it is regenerated) via only a single loop of the fluid loop (Fig. 2 discloses that this can be

accomplished by passing through the loop 10 once); a supply of dialysate; a chamber coupled to the fluid loop through which the dialysate can be fed at a feed rate into the fluid loop (88 allows the dialysate to be fed back into the fluid loop via the actions of the valves); a cycler (12) that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient (please note that the claim language does not require that the feed rate and circulation rates be specific rates as compared to other rates in the claim); and a discharge fluid path (fluid path leading to 46) coupled to the fluid loop through which the dialysate is drained from the fluid circuit at a discharge rate. Treu, however, does not disclose that the fluid is drained at a discharge rate that is less than the circulation rate allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. Roberts, however, discloses a similar fluid loop in which the fluid is drained at a rate less than the circulation rate thus allowing the fluid to circulate a plurality of times along the fluid loop prior to being drained (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. This paragraph also corresponds to the second paragraph in the second column of page 374 in which circulation rates and inflow/outflow rates are disclosed.). Therefore it would have been obvious to one of

ordinary skill in the art at the time of the invention to have modified Treu with the lower discharge rate as taught by Roberts, in order to allow the fluid to be used the maximum amount possible before being drained as waste. Also it is the examiner's position that it would be obvious to use the teaching by Roberts to drain the fluid at a rate that is slower than the circulation rate, as this is only a change to the rates at which the system/fluid flow is operated, and constitutes only finding an optimum value of a result effective variable which is routine in the art.

In reference to claim 14, Roberts discloses that the supply of dialysate contains about 25 liters or less of dialysate (Fig. 12, which is circuit that modified circuit of paragraph 2 is based on, uses 20 L of dialysate, which is less than 25 L).

In reference to claim 16, Roberts discloses that the circulation rate is about 300 ml/min or less (Roberts discloses in paragraph 1, col. 1 on page 377, the unmodified circuit in Fig. 12 uses a rate of 200 ml/min which is less than 300. Also, paragraph 2, col. 1, page 377 discloses using a rate of 200 ml/min):

In reference to claim 17, Roberts discloses that the chamber is capable of mixing and heating the dialysate (Fig. 7 and 12, specifically Fig. 12 discloses a heater).

In reference to claim 18, Treu discloses that the chamber (88) is coupled to the fluid loop via a fluid supply path (Fig. 2 discloses that the chamber is coupled to the fluid supply path as the fluid enters 88 after it passes through 78).

In reference to claim 19, Roberts discloses that the feed rate and the discharge rate are less than the circulation rate (paragraph 2, col. 1, page 377 discloses using inflow and outflow rates of 30 ml/min while using a higher circulation rate. Also see

paragraph 2, col. 2 of page 374 which discloses the same author cited as using a circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged).

In reference to claim 20, Treu discloses that the chamber is directly coupled to the fluid loop (Fig. 2 discloses that 88 is directly coupled to the fluid loop 10).

In reference to claim 22, Roberts discloses that the dialysate is continuously fled, circulated and drained over a treatment period of about 8 hours or less (paragraph 2, col. 1, page 377 discloses the fluid circuit referenced in claim 1, which is based off of the circuit in the paragraph above, which teaches an 8 hour treatment).

In reference to claim 23, Treu discloses that the chamber can be adapted to accommodate a variable increase in the dialysate during treatment (Fig. 2, 88 allows a variable increase which is monitored by 90).

Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu et al. (US Patent No. 6254567) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Treu discloses the device substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 2), the system comprising: a catheter having an inflow lumen and an outflow lumen (Fig. 2 discloses an embodiment which uses a double lumen catheter 18) in communication with the patient's peritoneal cavity (20); and a fluid circuit (Fig. 2) in fluid communication with the catheter, the fluid circuit including: a fluid loop (10), the fluid

loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (the dialysate follows the path through the loop 10 multiple times as it is regenerated); a supply of dialysate coupled to the fluid loop; a cycler (12) that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient (please note that the claim language does not require that the feed rate and circulation rates be specific rates as compared to other rates in the claim); a cleaning device (22) coupled to the fluid loop via a cleaning fluid path (the path includes entering the cleaning device via 32, flowing through the cleaning device and re-entering the fluid loop via 34) wherein the dialysate can be fed into the cleaning fluid path and cleaned at a cleaning rate prior to reintroduction into the fluid loop (please note that the claim language does not require that the cleaning rate be a specific rate relative to any other rate claimed, therefore the rate at which the fluid flows through the cleaning device is being interpreted as the cleaning rate); and a discharge fluid path (fluid path leading to 46) coupled to the fluid loop through which the dialysate is drained from the fluid circuit at a discharge rate. Treu, however, does not disclose that the fluid is drained at a discharge rate that is less than the circulation rate allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. Roberts, however, discloses a similar fluid loop in which the fluid is drained at a rate less than the circulation rate thus allowing the fluid to circulate a plurality of times along the fluid loop prior to being drained (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the

fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. This paragraph also corresponds to the second paragraph in the second column of page 374 in which circulation rates and inflow/outflow rates are disclosed.). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Treu with the lower discharge rate as taught by Roberts, in order to allow the fluid to be used the maximum amount possible before being drained as waste. Also it is the examiner's position that it would be obvious to use the teaching by Roberts to drain the fluid at a rate that is slower than the circulation rate, as this is only a change to the rates at which the system/fluid flow is operated, and constitutes only finding an optimum value of a result effective variable which is routine in the art.

In reference to claim 25, Treu discloses that the fluid loop is coupled to the supply of dialysate, the cleaning fluid path and the discharge fluid path via a cycler (12).

In reference to claim 26, Treu discloses that the cycler includes a fluid circuit coupled to a pumping mechanism and a plurality of valves such that the cycler is capable of automatically controlling the flow of dialysate into and out of the fluid loop during treatment (Fig. 2 discloses valves 80 and 92).

In reference to claims, 27 and 28, Roberts discloses that the cleaning device contains a sorbent material (Fig. 6 discloses using a sorbent cartridge) capable of non\-

selective removal of solutes from the dialysate prior to reuse and that the sorbent material is carbon (col. 1, paragraph 3, line 1).

In reference to claim 29, Treu discloses that the cleaning device contains an ion exchange resin (col. 1, line 24).

In reference to claim 30, Treu discloses the cleaning device contains a sorbent material capable of selective removal of solutes from the dialysate (col. 4, line 65).

Claim 3, 4, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Roberts discloses the device substantially as claimed .including the feed rate and the discharge rates being lower than the circulation rate (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. These rates of 200 and 36 are from the same researcher (Kraus et al.) that is being quoted in the second paragraph of col. 1, page 377). Roberts however, does not disclose that the feed and discharge rates are maintained equally at a rate that is either one-half or one-third of the circulation rate, such that the dialysate circulates either two or three times along the fluid loop. However, it would have been obvious to

one of ordinary skill in the art at the time of the invention to have modified Roberts such that the feed and discharge rates are either one-half or one-third the circulation rate, because it is a mere manipulation or arithmetic in order to derive a circulation of two or three times around the loop, and because it has been held that discovering an optimum value of a result effective Variable involves only routine skill in the art. In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments filed 11/13/2009 have been fully considered but they are not persuasive. Applicant argues that Roberts' disclosure teaches that the inflow and outflow rates are matched, and that it is physically impossible to create a recirculation flow rate higher than the inflow rate by limiting the outflow rate, and that Roberts' higher recirculation rate is due to the presence of a pump, which is different than Applicant's invention, which Applicant argues is to use the outflow discharge rate to create recirculation. Applicant argues that the presence of the pump in Roberts' disclosure is what creates recirculation. The examiner disagrees with this reasoning on several different levels.

First, the examiner would like to point out that it seems that Applicant is arguing that the only way Applicant's invention creates recirculation is through a discharge rate that is lower than the circulation rate. However, this argument does not appear to be supported by Applicant's specification or drawings.

The only places in Applicant's specification in which a discharge rate lower than a circulation rate is mentioned (paragraphs [0051], [0098], [0075], [0100]), the specification either discloses that the discharge rate is equal to the feed rate (paragraph [0051] and [0098]), or the discharge rate is higher than the feed rate (paragraph [0075]) or the discharge rate is lower than the feed rate (paragraph [0100]).

In the case where the discharge rate and feed rate are equal to each other but lower than the circulation rate, which is equivalent to what is disclosed by Roberts, Applicant argues that it is physically impossible to create a higher recirculation rate than the inflow rate by limiting the outflow rate, and that a pump must be used to provide the higher circulation rate. Applicant therefore argues that it is the pump that creates the high circulation rate and not the low discharge rate. Since in paragraphs [0051] and [0098] of Applicant's specification, Applicant discloses the same situation as Roberts' disclosure, it is therefore inherent that it is not solely Applicant's lower discharge rate that creates the higher circulation rate, but the addition of and presence of a pump, just as Roberts' teaches. Furthermore, the examiner has not found any of Applicant's figures to provide a schematic of a fluid circuit with out a pump/cycler present. Therefore it is the examiner's position that Applicant's lower discharge rate is not the sole provider/creator of a higher circulation rate, but is only one part of the system that acts to help provide a higher discharge rate.

In the case where the discharge rate is higher than the feed rate or lower than the feed rate (paragraphs [0075] and [0100], respectively), these portions of Applicant's disclosure and corresponding figures (4a and 4b)do not disclose a fluid circuit with out

the presence of pumps/cyclers to support Applicant's arguments that Applicant's lower discharge rate solely creates a higher circulation rate.

Furthermore, paragraph [0075] of Applicant's disclosure states "Any suitable and various number of pumps, valves, sensing devices and other suitable fluid circuit components can be utilized to control the flow of dialysate such that it can pass a multiple number of times into and out of the patient's peritoneum prior to discharge."

In summation, it is the examiner's opinion that Applicant does not have support in the specification or the drawings that the discharge rate being less than the circulation rate creates/allows/effects the dialysate to be circulated a plurality of times along the fluid loop prior to discharge.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767